

REMARKS

Applicants wish to first point out that the instant application does not claim priority to Germany 103-17-781.7 (4/16/2003), as erroneously indicated in the first paragraph under the heading "DETAILED ACTION."

Status of the claims

Claims 1-16 are pending. Claims 1 and 8-13 are allowed. Claims 2-7 and 14-16 are rejected.

Rejection under 35 USC 102

Claims 2-7 stand rejected under 35 USC 102(b) as allegedly being anticipated by Arison (5952347), Tung (5869673), and Belley (5565473). Applicants respectfully traverse.

Claim 2 is directed to pharmaceutical compositions comprising the novel Form B montelukast sodium of claim 1, and claims 3-7 are directed to the use of said novel Form B for treating various diseases/disorders. Arison teaches a metabolite of montelukast sodium; Tung teaches a method for the preparation of an intermediate in the synthesis of montelukast; and Belley teaches the compound montelukast sodium. None of the references teach or suggest the novel crystalline Form B montelukast sodium, a fact pointed out by the Examiner in the *Allowable Subject Matter* section of the office action. Since claim 1 is novel over the cited art, claims dependent on claim 1 having further limitations must also be novel. Applicants respectfully request the Examiner clarify how the cited references can anticipate claims 2-7 when they are missing the key element of the claims, namely Form B montelukast sodium as described and claimed in claim 1.

In view of the above remarks, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection under 35 USC 112

Claims 14-16 stand rejected under 35 USC 112, second paragraph as allegedly being indefinite. The Examiner required clarification with respect to the process being claimed as well as with Form A montelukast sodium.

Form A montelukast sodium is the crystalline form described in US 5,614,632 (see page 1, lines 10 -11 of the instant specification), and its X-ray powder diffraction peak positions are provided in the Table on page 2 of the instant specification. With respect to the process being claimed, there is no missing steps; thus, when acetonitrile is removed from montelukast sodium:acetonitrile monosolvate the resulting substance is Form A montelukast sodium that is substantially free of amorphous montelukast; there is no additional step necessary to remove unwanted forms of montelukast sodium.

In view of the above remarks, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Applicants believe that in light of the above remarks the application is now in condition for allowance. An early favorable action is respectfully requested.

Respectfully submitted,

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